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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/537,088	03/29/2000	Anil Kumar Dwivedi	82239	7351

7590 08/19/2003

Nath & Associates  
1030 Fifteenth Street, N.W.  
Washington, DC 20005

EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 08/19/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/537,088

Applicant(s)

DWIVEDI ET AL.

Examiner

Jeffrey E. Russel

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

THE REPLY FILED 04 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 04 August 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.

Claim(s) objected to: None.

Claim(s) rejected: 1-6,8,9,11,14 and 15.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

1. The amendment after final rejection filed August 4, 2003 will be entered. The claims remain rejected for the same reasons set forth in the final Office action mailed February 3, 2003. The examiner maintains his position for the reasons of record.
2. Chiesi et al's acid component would not materially affect the basic and novel characteristics of Applicants' claimed composition because Chiesi et al's acid component is useful in improving the storage stability, the water solubility, and the bioavailability of compositions which can be orally administered. These characteristics and functions are fully consistent with the basic and novel characteristics of Applicants' claimed compositions. If Applicants intend to exclude an acid component from their claimed compositions, Applicants may wish to consider inserting claim limitations which explicitly exclude such a component. Page 4, lines 15-17, of Applicants' specification may constitute written descriptive support for such a negative claim limitation. Such a limitation would overcome the rejection based upon the Nath et al article in view of Chiesi et al.
3. Concerning the data set forth at page 13 of Applicants' response, the data can not be relied upon to establish criticality for the claimed molar ratio range because the data was not submitted in appropriate form under 37 CFR 1.132. Further, even if submitted in the form of an affidavit or declaration under 37 CFR 1.132, it is not clear that the data would be sufficient to rebut the prima facie case of obviousness because the data does not indicate what peptide was tested, the data does not test the specific cyclodextrin derivatives taught by Chiesi et al, and the data does not test molar ratios both within and outside of Applicants' claimed range (see MPEP 716.02(d) under "Demonstrating Criticality Of A Claimed Range"). The submitted data is also not commensurate in scope with the rejected claims, and especially with claims 11 and 15, which

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do not require oral administration. Finally, Applicants' argument that the currently claimed molar ratio is "essential" for biological activity after oral administration is contradicted by the fact that the original disclosure indicates that the range is preferred, not "essential". Note the lack of any such range, e.g., in originally-filed claim 1.

4. The European Patent Application 463,653's preference for nasal administration does not prevent the rejection of Applicants' claims, which embrace nasal administration (see claim 11). In any event, the European Patent Application '653 teaches oral administration at column 7, lines 16-17. The examiner does not question that Applicants' compositions are effective for oral administration; however, Applicants have not supplied any evidence contradicting the statement at column 7, lines 16-17, that the compositions of the European Patent Application '653 are effective oral administration.

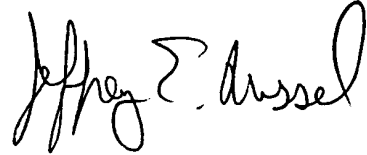
5. Applicants argue that column 25, lines 3-6, of Hora et al does not constitute an enabling disclosure for the formation of inclusion complexes. However, prior art references are presumed enabling, and Applicants have not submitted any evidence or scientific reasoning to support their assertion that one of ordinary skill in the art can not form inclusion complexes by following the disclosure of Hora et al.

6. The examiner has nowhere admitted that the French Patent '268 "teaches away" from Applicants' claimed complexes.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Technology Center 1600 for formal communications is (703) 872-9306; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1600 receptionist is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Jeffrey E. Russel". The signature is fluid and cursive, with the first name "Jeffrey" and last name "Russel" clearly distinguishable.

Jeffrey E. Russel

Primary Patent Examiner

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JRussel

August 19, 2003